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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,214	01/27/2006	Hisashi Nagamoto	05273.0099	1021

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EXAMINER	
PAGONAKIS, ANNA	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,214	NAGAMOTO ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

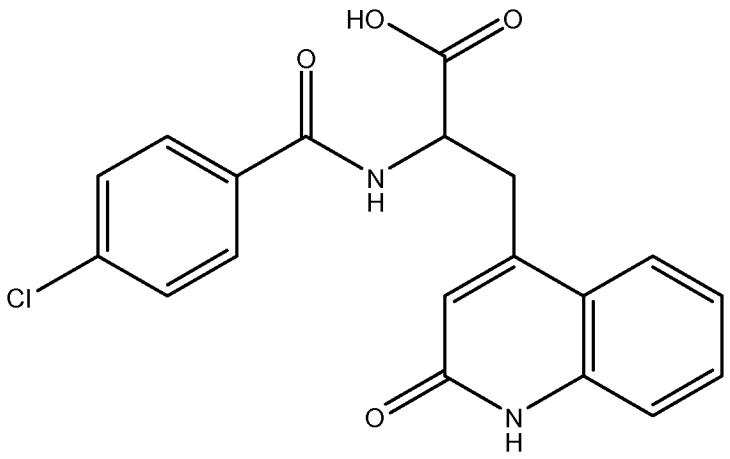
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 sheets; 3/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group II, claims 8-12, and the compound of claim 12 (depicted below):



in the reply filed on 2/7/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

This application is the US entry of PCT/JP04/09992 filed on 7/7/2004; and claims priority benefit of foreign priority document JAPAN 2003-282691 filed 7/30/2004 and JAPAN 2004-021808 filed 1/29/2004; it is noted that a certified copy of these foreign priority documents have not been filed as required under 35 U.S.C. 119(b); further it is noted that currently an English language translation of these foreign priority documents have also not been filed.

Accordingly, claims have been 13-15 have been added, 1-9 have been cancelled, no claims have been amended or withdrawn.

Claims 10-15 are presently under examination and are the subject of this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim10, 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 13 and 14 are directed to the method of claim 10 and 11, respectively where the patient has xerostomia accompanying Sjogren's syndrome.

In particular, the specification fails to provide adequate written description for accelerating salivation associated with Sjogren's Syndrome. and a prophylactic and/or treating effect of xerostomia associated with Sjogren's Syndrome.

MPEP 2163 states, "The issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the application had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not convention in the art or known to one of ordinary skill in the art.... The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re

Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co., Inc. 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))….Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to hose skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. cir. 1991)."

Applicant states in claims 13 and 14, simply that the invention further can be used to treat patients with Sjogren's syndrome in need of acceleration of salivation and xerostomia accompanied with Sjogren's syndrome. No specific mechanism of action or results of findings have been provided by Applicants that in fact the Sjogren's syndrome can treated with claimed method 10 and 11, respectively.

As stated in MPEP 2163, "the subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally field, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the art that Applicant had possession of the concept of administering the presently claimed compound of the treatment of any disorder

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Considering that claims 10-15 are drawn to a method of prophylaxis and/or treatment of xerostomia by administration of the elected compound, the said claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method of treating xerostomia does not reasonably provide enablement for a method of preventing xerostomia.

The specification does not enable any skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In Re Wands, 8 USPQ2nd 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are herein discussed in view of the instant invention.

<u>The nature of the invention</u>

Applicant claims a method of preventing or xerostomia by administration of the elected compound.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e., what compounds can treat or prevent which specific disease). There is no reasonable predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge would prevent one of ordinary skill in the art from accepting any therapeutic or preventative regimen on its face. Moreover, there is no prior art disclosing the prevention of said disease.

The instant claimed invention is highly unpredictable as discussed blow. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the prevention of said disease is highly unpredictable since one skilled in the art would need to carry out experimentation to determine if the claimed compound is capable of prevention of xerostomia. Moreover, the specification lacks to show a method of treating said subjects need to undergo in order to prevent said disease.

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability of the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine a method of determining the subjects that would certainly suffer from the said conditions or diseases as a method for showing that method

wherein the said subjects are subjected to the claimed compounds in order to achieve the claimed prevention.

Thus, the specification fails to provide sufficient support for said prevention methods. Thus, one of skill in the art would have to perform an exhaustive experimentation in order to practice the claimed compounds.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2nd 1001, states "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion," and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test whether the said disease can be prevented in instant claims, with no assurances of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al (US 5,476,858) and Loguercio et al (Digestion 36: 91-95 (1987).

Yamasaki et al. disclose the use of the elected compound (see claim 2) for its use in treating diseases associated with a decrease of somatostatin (abstract), more particularly it relates to a pharmaceutical composition useful for increasing secretion of somatostatin (column 1, first paragraph). The agent is in the form of pharmaceutical preparations including tablets, pills and powders and appropriate excipients (column 2, paragraphs 1 and 2).

Yamasaki et al. is silent of the capability of the elected compound as an accelerator of salivation.

Loguercio et al. teach that the administration of a somatostatin, in this case pentagastrin, increases salivary secretion progressively depending on dose (abstract).

Loguercio et al. is silent on the use of the elected compound leading to the acceleration of salivation.

Accordingly, one of ordinary skill in the art would have found it prima facie obvious to use the elected compound for accelerating salivation as taught by Loguercio et al. because the skilled artisan would have reasonably expected the same or substantially similar level of increase in salivation from this compound as would have been expected from the use of the somatostatin.

This reasonably expectation of success is further supported by the teachings of Yamasaki et al. that the elected compound acts as an agent increasing somatostatin. Loguercio et al. teach that a somatostain in turn increases salivation. Therefore, one of ordinary skill in the art would reasonably

expect that an agent, such as the elected compound, known to increase somatostatin would further lead to accelerated salivation given that somatostatin is known to do so.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614